

**REMARKS**

Claims 21-47 are pending. Claims 21-38 are allowed. Claims 39 - 47 stand rejected. Claim 39 has been amended to recite “and wherein the distal ends of the at least two staple members” are substantially parallel to the central axis when the device is in the first configuration. Support for this amendment may be found in claim 21 which is essentially the device to which the system of claim 39 is directed to.

Claims 39-47 were rejected under 35 USC §112, second paragraph, as being indefinite to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants submit that the above referenced amendment to independent claim 39 adds clarity to the subject matter regarded by Applicants as the invention as the amendment relates to the feature that the distal end of the at least two staples are substantially parallel to the central axis when the device is in the first configuration. Therefore, the rejection rejected under §112 is respectfully requested to be withdrawn.

Claims 39-45 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Tovey (U.S. Patent No. 5,478,354). Applicants respectfully traverse the rejection.

Independent claim 39 requires a system for engaging tissue having a preexisting opening comprising a device comprising a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and a member configured to be disposed within the ring; and wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the ***member is configured to bias the distal ends of the at least two staple members*** and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration.

The Examiner references Tovey relative to the claimed invention. In particular the Examiner contends that Tovey discloses:

..... “the claimed invention including a device 50 comprising an annular ring 55 and at least two (three are illustrated) equally spaced staple members 52-54 and 56-58 extending therefrom (see, e.g., Figs. 3, 4 and 6 and col. 4, lines 1-21). The ring is disposed about a central axis. Each of the staple members has a distal end. A member, e.g., 69, is configured to be disposed within the ring. The member is movable along the central axis relative to the ring. The device has a first configuration where the member is disposed within the ring (e.g., while installing the ring) and a second configuration where the member is not disposed within the ring (e.g., after installation is complete). The distal ends of the at least two staple members are substantially parallel to the central axis in a first configuration (e.g., Fig. 3) and the distal ends of the at least two staple members are substantially orthogonal to the central axis in a second configuration (e.g., Fig. 6). The device can be formed of a superelastic material such as a shape-memory titanium (*sic*) alloy (see e.g., col. 2, lines 4-6 and col. 4, lines 27-30). A driver, e.g., 67, is disposed about (i.e. along or near) the member and is movable with respect to the member. The driver is configured to move the ring from a first position relative to the member to a second position relative to the member, whereat the at least two staple members engage tissue.”

However, Tovey fails to identically disclose the claimed invention in at least that Tovey does not disclose a member “***configured to bias the distal ends of the at least two staple members..... when the device is in the first configuration.***” The Examiner reasons that “member 69 can be configured to bias the distal ends of the staple members....at least it provides the necessary resistance and support to the staple member against which the driving means acts (see, e.g., col. 4, lines 17-21)”. However, the Examiner’s reasoning that “member 69 ***can be configured*** to bias the distal ends of the staple members” is not the “identical disclosure” standard required by § 102. For this reason alone, the Examiner’s rejection under §102(e) is improper and is respectfully requested to be withdrawn. Moreover, it appears that any biasing that Tovey discloses can at best be said to disclose member 69 biasing against the inner ring section 55 of device 50 and not the distal ends (58 and 59) as shown in Fig. 3. To conclude otherwise is not supported and an improper basis for the finding of anticipation under § 102.

Since claims 40-45 depend from claim 39, the Examiner is respectfully requested to withdraw the rejection of claims 39-45 under §102(e).

Claims 46 and 47 stand rejected under 35 USC § 103(a) as being unpatentable over Tovey. Applicants respectfully traverse the rejection.

Claims 46 and 47 depend from amended claim 39 and require a member “***configured to bias the distal ends of the at least two staple members..... when the device is in the first configuration.***” As noted above, it is this biasing member that is not disclosed nor suggested in Tovey. The Examiner reasons that it is in the purview of one skilled in the art to extend the staple members “from an inner periphery of a ring member”. However to accept the Examiner’s argument would render the device 55 of Tovey inoperable. That is to say that the tabs 62, 63, 64 of driving means 60 would not be able to close legs 58 and 59 of device 55 according to Fig. 3. Accordingly, Applicants seek withdraw of the rejections of claims 46 and 47 in view of Tovey.

For the foregoing reasons, Applicants submit that claims 39-47 are allowable over the cited art, and request the Examiner to withdraw the rejections.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Should the Examiner desire to discuss this response in an effort to advance the prosecution of this case, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

By: /Theodore J. Shatynski/  
Theodore J. Shatynski  
Reg. No. 36,676

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2498  
Date: March 26, 2010